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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,569	12/22/2003	Arnold L. Demain	P-8472-US	7974
49443	7590	10/18/2006	EXAMINER	
PEARL COHEN ZEDEK, LLP PEARL COHEN ZEDEK LATZER, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/743,569	Applicant(s) DEMAIN ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of group III, claims 21-25 on 7/12/06 is acknowledged.

Claims 21-25 are being considered on the merits. Claims 1-20 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is vague and indefinite in the recitation of “substantially free” with respect to “animal products”. The extent of “substantially” is unclear, even when reading the claim in light of the specification. No definition is provided for “substantially free of animal products”. Are animal products present as 1%, 10%, 15%, 49% etc. of the culture medium?

Claim 22 is confusing in the recitation of “a compound derived from a vegetable” It is uncertain how a compound is “derived” in this context. Is it functional, chemical or physiological derivation, for example?

Claim 24 is confusing and incorrect in that “hydrolyzed soy” is not a “compound” but rather a complex mixture of various compounds.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 22 and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Castell (I) (<http://jb.asm.org/cgi/reprint/43/4/473.pdf>, 1941, accessed 8/10/06) or Castell (II) (1941 Powdered grass as an enrichment medium for acid-forming anaerobes. J. Bact., 43: 463-471).

The claims are directed to a culture medium substantially free of animal products and containing *C. difficile*.

Castell (I) and (II) each discloses a culture medium substantially free of animal products and containing *C. difficile*, comprising a compound derived from a vegetable and an iron source. See, e.g., Table 1, respectively, Table 2, page 466.

Claims 21, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Saif et al., (The Journal of Medical Microbiology, Vol 45, Issue 2 133-137).

The claims are directed to a culture medium substantially free of animal products and containing *C. difficile*.

Saif *et al.* disclose various culture media substantially free of animal products and containing *C. difficile*, comprising a compound derived from a vegetable and an iron source. See, e.g., pages 135-136. Any medium that supports *C. difficile* is deemed a culture medium therefor.

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Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castell (I) or (II) taken with Ingram (U.S. Patent No. 6,130,076).

Castell (I) and (II) each discloses a culture medium substantially free of animal products and containing *C. difficile*, comprising a compound derived from a vegetable and an iron source. See, e.g., Table 1, respectively, Table 2, page 466.

The reference differs from the claimed invention in that a grass extract rather than soy beans or a soy hydrolyzate are used in the medium. However, Ingram adequately demonstrates that the use of soybean products, including soy hydrolyzates are old and well known as suitable ingredients in bacteriological culture media.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the culture media of Castell (I) and (II) by adding a soy hydrolyzate as an additional source of nutrients as taught by Ingram for the expected benefit of providing a nutrient medium richer in non-animal proteins for the cultivation of *C. difficile*, for example.

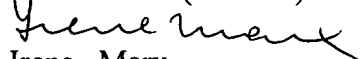
Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651